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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/842,161  | 04/26/2001  | Hidetaka Iwai        | 206580US0           | 6889             |
| 22850   | 7590        | 09/09/2005           | EXAMINER            |                  |
| OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.<br>1940 DUKE STREET<br>ALEXANDRIA, VA 22314 |             |                      | YU, GINA C          |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1617                |                  |

DATE MAILED: 09/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/842,161

Applicant(s)

IWAI ET AL.

Examiner

Gina C. Yu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 2 and 4-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Applicant's submission filed on January 24, 2005 has been entered. Applicants' claim amendment overcame the claim rejection made under 35 U.S.C. § 112, ¶ 2<sup>nd</sup> which was indicated in the previous Office action dated September 22, 2004. Claim rejections made under 35 U.S.C. § 103(a) as indicated in the same Office action are withdrawn in view of the claim amendment. New rejections are made.

#### *Claim Rejections - 35 USC § 103*

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Claims 1, 2, 6-8, 10-21, 27-29, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu (JP 63-126542).**

Yu teaches transparent microemulsions containing hydrophilic ionic surfactants and oil components used for pharmaceuticals and cosmetics. See English Translation, p. 2, lines 1 -17; p. 7, lines, 9-10. The reference teaches that the ratio of the nonionic surfactant to the oil ingredients in the invention may range from 1:05 to 1:10, and the emulsified particle size is 0.01-0.1 microns. See instant claims 1 and 3. See p. 4, lines 11-12. The application of the invention, such as liquid detergent, shampoo, hair tonic, etc, are disclosed in p. 7, lines 19-24. See instant claims 18 and 19.

The reference teaches anionic surfactants, cationic, amphiphilic surfactants, or mixture of thereof in p. 4, line 12 – p. 5, line 5. See instant claims 11-13. The reference teaches N-acylglutamic acid salts and specifically teaches monosodium N-lauroyl glutamate, disodium N-stearoyl glutamate, monosodium N-myristearyl-L-glutamate. See p. 4, fifth paragraph; instant claims 27. Sodium N-myristoyl-N-methyltaurine is taught. See p. 4, 4<sup>th</sup> par; instant claim 29. While the Yu reference does not teach dynamic surface tension of these surfactants, examiner notes that, since the prior art surfactants are the same compounds used in applicants' invention, and these prior art surfactants also have the dynamic surface tension that meets the recited requirement. For claim 31, the recited surfactants are disclosed in Example 31 and p. 4, 4<sup>th</sup>-5<sup>th</sup> par.

Although Yu does not disclose any specific example formulation having the ratio of oil to hydrophilic surfactants that is "more than 11.67", the ratio of 10:1 is taught by the reference. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The Yu reference teaches making a stable and transparent microemulsion with the nonionic surfactants recited by applicants and the oil: nonionic surfactant that is close to the applicants' range. Also taught are the various organic and silicone oils that can be used alone or mixed in the oil phase, in an amount up to 60 % wt.

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Given these conditions, a skilled artisan would have found an optimal ratio between oil and hydrophilic surfactant ratio by routine experimentations.

As for claims 1, 6, 7, and 15, the process limitations are obvious in view of the Yu reference teaching, in p. 7, lines 4- 8, to use a high pressure homogenizer or ultrasound emulsifying machine to produce strong shear stress of 400 atm or higher, or preferably of 600 atm or higher at a temperature below 50 °C. See instant claim 20. Examiner takes the position that employing the prior art equipments would obviously produce the shearing rate of the instant claims, unless proven otherwise.

**Claims 4, 5, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu as applied to claims 1-3, 6-8, 10-21, 27-29, and 31 above, and further in view of Drapier et al. (US 6121228) ("Drapier").**

Yu further teaches that while liquid oils are preferred, oils in solid state may be used if they become liquid when mixed, suggesting mixing liquid and solid fatty components. See p. 5, line 6 – p. 6, last line. See also Tables for high alcohols, such as isostearyl alcohol, showing satisfactory transparent microemulsions. The Yu reference fails to teach an example of composition having both solid and liquid oil with specific viscosity.

Drapier teaches water-in-oil microemulsion liquid detergent having viscosity ranging from 6-300 milliPascal. See col. 4, lines 47 – 67; col.14, lines 17 - 26.

Given the teaching in Yu that the both liquid and solid oils may be used for variety of microemulsion applications such as liquid detergents, and the teaching that thickening agents may be added in the compositions, it would have been obvious to one having ordinary skill in the art to have expected successfully producing a product having desired viscosity by routine experimentations. The routineer who contemplates to formulate the liquid detergent according to Yu would have been motivated to adjust the viscosity as taught by Drapier.

**Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yu as applied to claims 1-3, 6-8, 10-21, 27-29, and 31 above, and further in view of Ansel (Pharmaceutical Dosage Forms and Drug Delivery Systems, 1990 5<sup>th</sup> ed.).**

While Yu teaches that the HLB of the ionic surfactants should be hydrophilic since it is necessary to obtain oil-in-water type microemulsions, the reference fails to teach HLB of the surfactants.

Ansel teaches that surfactants having HLB of 8-18, and particularly HLB of 15-18 produce transparent microemulsion compositions. See Ansel, p. 244 col. 2, lines 9-13.

Given the general teaching of formulating o/w microemulsion compositions in Yu, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have been motivated to look to the prior

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arts such as Ansel for specific types and characteristics of the emulsifiers conventionally used in microemulsions.

**Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yu as applied to claims 1-3, 6-8, 10-21, 27-29, and 31 above, and further in view of Gers-Barlag et al. (US 5876702) ("Gers-Barlag").**

The Yu reference fails to teach the surface tension of the oil components.

Gers-Barlag teaches that o/w microemulsions are obtained from oil components having surface tension of less than 30 mN/m. See col. 17, lines 15 - 30. The reference teaches that oils having a polarity between 10-20 mN/m are preferred. See also col. 17, lines 31 - 46 for specific types of oils.

Given the general teaching of formulating o/w microemulsion compositions in Yu, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have been motivated to look to the prior arts such as Gers-Barlag for specific types and characteristics of oils conventionally used in microemulsions.

**Claims 23 and 25 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Yu as applied to claims 1-3, 6-8, 10-21, 27-29, and 31 above, and further in view of Diec et al. (US 6468551 B1) ("Diec").**

Yu, discussed above, fails to teach using silicone oil in the microemulsion.

Diec teaches cosmetic o/w microemulsions comprising hydrophilic o/w emulsifiers. See Example 22, comprising oil and the emulsifier in the weight

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ratio of greater than 10:1. See also col. 45, lines 31-39. The reference teaches that silicone oils are “advantageously” used in the invention, particularly mentioning polydimethylsiloxanes. See col. 25, lines 43 – 53. See instant claim 23 and 25.

Given the general teaching of formulating o/w microemulsion compositions in Yu, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have been motivated to look to the prior arts such as Diec for specific types oils conventionally used in microemulsions for cosmetic purposes. The skilled artisan would have expected to successfully produce a cosmetically advantageous composition.

**Claims 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu as applied to claims 1-3, 6-8, 10-21, 27-29, and 31 above, and further in view of Brunetta et al. (US 5562911) (“Brunetta”).**

Yu, discussed above, fails to teach fluoro-based oil.

Brunetta teaches that due to the formation of protective film on skin, the use of perfluoropolyether in cosmetic formulation is well known in the art. See col. 1, lines 15 – 56.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have substitute the oil in the Yu formulation with perfluoropolyether as motivated by Brunetta, because of the expectation of successfully producing a o/w microemulsion which forms protective film on the skin.



**Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yu as applied to claims 1-3, 6-8, 10-21, 27-29, and 31 above, and further in view of Shiojima et al. (US 6066316) ("Shiojima").**

While the Yu reference teaches that nonionic surfactants are used to make microemulsions, the reference fails to teach polyoxyethylene alkyl ethers. See translation, p. 2, 3<sup>rd</sup> par.

Shiojima teaches a transparent oil-in-water hair cosmetic composition comprising POE behenyl ether. See col. 48, Test Example 22. The formula contains 32.5 % by weight of oil phase (Carnauba wax and liquid petrolatum) and 3.0 % of POE-10 behenyl ether, meeting the weight ratio requirement of instant claim 1.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the invention of Yu by substituting the hydrophilic surfactants with POE-10 behenyl ether as motivated Shiojima because of an expectation of successfully producing cosmetic compositions with similar effects or hair cosmetic emulsion compositions.

#### ***Response to Arguments***

Applicant's arguments with respect to claims 1, 2, and 4-31 have been considered but are unpersuasive.

Applicants argue that Yu does not suggest selecting of a surface active agent having a dynamic surface tension of 57 mN/m or less to make an emulsion

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of oil:surfactant ratio of 11.67:1. Applicants also argue that the declaration filed on July 16, 2004 should be considered as a probative evidence of unexpected results in this case. Examiner respectfully disagrees for the reasons as discussed in the previous Office action dated September 22, 2005. While it is true that Yu does not teach the dynamic surface tension of each surface active agents, examiner respectfully points out that the claimed surfactants are nevertheless disclosed in the prior art. The claimed surfactants act to reduce the surface tension of the oil, and are taught to be useful to make microemulsion in the condition as recited by applicants (i.e., oil: surfactant ratio, particle size).

Applicants indicate that the prior art surfactants used in the example formulation have dynamic surface tension slightly above 57 mN/m, and suggest that low transparency is obtained by using these surfactants in a particular formulation shown in declaration p. 2. Examiner is not convinced that such finding amounts to unexpected or surprising results that negates the prima facie obviousness in this case. Dynamic surface tension is time dependent and a measurement of the surfactant to reduce the surface tension at the interface of the liquids. The rejection is made in view of the strong teachings of the reference that the claimed surfactants are well known in microemulsion art. It is still viewed that the claimed invention is an obvious variation of the prior art, since applicants are using the surfactants that are disclosed in the prior art in the weight ratio that is close to the 10:1 ratio that is also taught by the prior art.

*Conclusion*

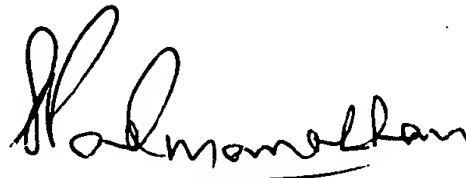
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 571-272-0635. The examiner can normally be reached on Monday through Friday, from 8:30 AM until 6:00 PM..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gina Yu  
Patent Examiner

  
SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER